

Patent  
10/767,782

### IN THE CLAIMS

Please cancel Claims 44, 46, 47, 49, 60 and 63 without prejudice and without disclaimer of subject matter.

Please amend Claims 50-53 as indicated.

1. (Previously Presented) A method of controlling the administration of a thermal therapy, comprising:
  - inserting a catheter having a heat transfer element positioned at a distal tip of the catheter into a blood vessel of a patient, the catheter having a supply lumen for supplying a working fluid to the heat transfer element and a return lumen for returning a working fluid from the heat transfer element;
  - circulating a working fluid through the catheter and the heat transfer element, the working fluid having a temperature different from the patient temperature;
  - receiving a signal from a temperature sensor mounted at or adjacent the distal tip of the heat transfer element;
  - determining a control temperature based on the signal;
  - using the control temperature to control the temperature of the working fluid, and
  - circulating a working fluid and not determining a control temperature, for a predetermined period of time based on the difference between a current patient temperature and a target patient temperature.
2. (Original) The method of claim 1, further comprising causing the working fluid to stop circulating, and wherein the receiving includes:
  - allowing a first interval of time to pass;
  - collecting data from the temperature sensor during a second interval of time,
  - such that the allowing and collecting each follow the causing.
3. (Original) The method of claim 1, wherein the temperature sensor is selected from the group consisting of thermistors, thermocouples, and combinations thereof.

**Patent  
10/767,782**

4. (Original) The method of claim 3, wherein the temperature sensor is two thermistors, and further comprising receiving a safety monitor signal from one of the two thermistors.
5. (Original) The method of claim 4, further comprising causing the working fluid to stop circulating if a value of control temperature measured by the safety monitor signal falls outside a predetermined range.
6. (Original) The method of claim 5, wherein the predetermined range is 31oC to 37oC.
7. (Original) The method of claim 2, wherein no data is collected during the first interval.
8. (Original) The method of claim 7, wherein data is collected during the second interval at a predetermined frequency.
9. (Original) The method of claim 2, wherein the first interval is between about 5 and 15 seconds.
10. (Original) The method of claim 9, wherein the first interval is between about 10 and 12 seconds.
11. (Original) The method of claim 2, wherein the second interval is between about 10 and 30 seconds.
12. (Original) The method of claim 11, wherein the second interval is between about 15 and 25 seconds.

**Patent**  
**10/767,782**

13. (Original) The method of claim 1, wherein the temperature sensor is disposed in a polymer tube.

14. (Original) The method of claim 1, wherein the temperature sensor is a thermistor.

15. (Original) The method of claim 13, wherein the polymer is polyamide.

16. (Original) The method of claim 2, wherein the first interval is about the same length of time as the second interval.

17. (Original) The method of claim 2, wherein the first and second intervals are different lengths of time.

18. (Original) The method of claim 2, further comprising integrating a value of the signal over the first interval with respect to time to derive a first area.

19. (Original) The method of claim 18, further comprising integrating a value of the signal over the second interval with respect to time to derive a second area.

20. (Original) The method of claim 2, wherein the second interval of time is at least one minute.

21. (Original) The method of claim 2, wherein the time during which the working fluid is caused to stop circulating, divided by the sum of the time during which the working fluid is caused to stop circulating plus the time during which the working fluid is circulating, is greater than about 90%.

22. (Canceled)

**Patent  
10/767,782**

23. (Previously Presented) The method of claim 1, wherein the working fluid has a temperature below the current patient temperature, and wherein the predetermined period of time is greater than about 30 minutes.

24. (Previously Presented) The method of claim 1, wherein the working fluid has a temperature above the current patient temperature, and wherein the predetermined period of time is greater than about 15 minutes.

25. (Previously Presented) The method of claim 1, wherein the predetermined period of time is directly proportional to the difference between the current patient temperature and the target patient temperature.

26. (Previously Presented) The method of claim 1, wherein the circulating includes circulating the working fluid at a maximum pump speed.

27. (Previously Presented) The method of claim 1, wherein the circulating includes circulating the working fluid at a power of pump speed which is proportional to the difference between the current patient temperature and the target patient temperature.

28. (Previously Presented) The method of claim 1, wherein the predetermined period of time is determined by the initial patient temperature minus the sum of the target patient temperature and a constant, divided by the maximum rate of change of temperature, pertaining to a desired thermal therapy.

29. (Original) The method of claim 28, wherein the desired thermal therapy is inducing hypothermia.

30. (Original) The method of claim 28, wherein the desired thermal therapy is rewarming.

Patent  
10/767,782

31. (Original) The method of claim 19, further comprising dividing the first area by the second area to calculate a value that is a function of a time constant of an exponential function.

32. (Original) The method of claim 31, further comprising constructing a look-up table for the function of the time constant and the results of the division of the first area by the second area.

33. (Original) The method of claim 32, further comprising determining a magnitude of the exponential function using the first area, the second area, and the time constant.

34. (Original) The method of claim 33, wherein the determining further comprises calculating the projected control temperature based on the signal from the temperature sensor as measured at the end of the second interval, the magnitude of the exponential function, and the time constant of the exponential function.

35. (Original) The method of claim 2, wherein the determining includes:  
assuming a range of time constants for an exponential;  
performing a least squares fit between the collected data and the exponential for each of the range of time constants to calculate an error value that is a function of the time constant; and  
minimizing the error value to determine a unique value of the time constant.

36. (Original) The method of claim 35, further comprising using the unique value of the time constant to determine the projected control temperature.

37. (Original) The method of claim 35, further comprising determining the magnitude of the exponential.

38. (Original) The method of claim 35, further comprising determining a first-order linear component and adding the first-order linear component to the exponential to determine the projected control temperature.

**Patent  
10/767,782**

39. (Original) The method of claim 38, further comprising determining a higher-order components and adding the higher-order components to the exponential to determine the projected control temperature.

40. (Original) The method of claim 38, further comprising administering an anti-shivering agent to the patient.

41. (Original) The method of claim 1, wherein the temperature sensor is encapsulated in a metal tube.

42. (Canceled)

43. (Canceled)

44. (Canceled)

45. (Canceled)

46. (Canceled)

47. (Canceled)

48. (Previously Presented) A heat transfer catheter for inducing a therapeutic state of hypothermia in a patient, for maintaining the temperature of a patient, or for rewarming a patient,, comprising:

a catheter having a proximal end capable of being coupled to an input of a source of working fluid and a distal end coupled to a heat transfer element;

a supply lumen disposed within the catheter, the proximal end of the supply lumen capable of being coupled to an output of a source of working fluid and a distal end terminating at or within the heat transfer element; and

a temperature sensor disposed on or within the heat transfer element,

wherein the temperature sensor is coupled to signal lines that extend to the proximal end of the catheter via the return lumen, supply lumen, both, or within the return lumen, supply lumen, or both.

Patent  
10/767,782

49. (Canceled)

50. (Currently Amended) ~~The catheter of claim 49~~ A heat transfer catheter for inducing a therapeutic state of hypothermia in a patient, for maintaining the temperature of a patient, or for rewarming a patient, comprising:

a catheter having a proximal end capable of being coupled to an input of a source of working fluid and a distal end coupled to a heat transfer element;

a supply lumen and a return lumen disposed within the catheter, the proximal end of the supply lumen capable of being coupled to an output of a source of working fluid and a distal end terminating at or within the heat transfer element;

a guidewire lumen disposed within the catheter, the guidewire lumen coupled to the supply lumen, the supply lumen terminating proximal of the guidewire lumen; and

a temperature sensor disposed on or within the heat transfer element,

wherein the supply and return lumens are coaxial, and

wherein the temperature sensor is mounted on the guidewire lumen distal of the termination of the supply lumen.

51. (Currently Amended) The catheter of claim 49 50, wherein the distal tip of the guidewire lumen is coupled to the distal tip of the heat transfer element.

52. (Currently Amended) The catheter of claim ~~[[44]]~~ 50, wherein the temperature sensor is encapsulated in a polymer tube.

53. (Currently Amended) The catheter of claim ~~[[44]]~~ 50, wherein the temperature sensor is encapsulated in a metal tube.

54. (Original) The catheter of claim 48, wherein the temperature sensor signal lines are in the return lumen from the proximal end of the catheter to near the distal end of the catheter and the proximal end of the heat transfer element, at which point they traverse to the supply lumen.

Patent  
10/767,782

55. (Previously Presented) A heat transfer catheter for inducing a therapeutic state of hypothermia in a patient, for maintaining the temperature of a patient, or for rewarming a patient,, comprising:

a catheter having a proximal end capable of being coupled to an input of a source of working fluid and a distal end coupled to a heat transfer element;

a supply lumen disposed within the catheter, the proximal end of the supply lumen capable of being coupled to an output of a source of working fluid and a distal end terminating at or within the heat transfer element; and

a temperature sensor disposed on or within the heat transfer element,

wherein the heat transfer element includes at least two heat transfer segments separated by a flexible joint.

56. (Original) The catheter of claim 55, wherein the flexible joint includes bellows.

57. (Original) The catheter of claim 55, wherein the heat transfer segments are smooth.

58. (Original) The catheter of claim 55, wherein the heat transfer segments have ridges.

59. (Original) The catheter of claim 55, wherein the heat transfer segments have helical ridges and grooves.

60. (Canceled)



**Patent  
10/767,782**

61. (Previously Presented) A heat transfer catheter for inducing a therapeutic state of hypothermia in a patient, for maintaining the temperature of a patient, or for rewarming a patient, comprising:

a catheter having a proximal end capable of being coupled to an input of a source of working fluid and a distal end coupled to a heat transfer element;

a supply lumen disposed within the catheter, the proximal end of the supply lumen capable of being coupled to an output of a source of working fluid and a distal end terminating at or within the heat transfer element; and

a temperature sensor disposed on or within the heat transfer element,

wherein the heat transfer element includes a straight supply lumen and a helical return lumen, the helical return lumen encircling the straight supply lumen.

62. (Original) The catheter of claim 61, wherein the heat transfer element includes a straight supply lumen and multiple helical return lumens, the multiple helical return lumens encircling the straight supply lumen.

63. (Canceled)